K003672 page 1 of 2

FEB 2 2 2001

510(k) SUMMARY

SUBMITTED BY:	Medge Platforms Inc. 90 Park Avenue, 17th Floor New York, NY 10016-1301

(Please note the above is a legal address for our company until a physical facility is set up and registered with the Agency).

CONTACT PERSON:	Gustavo Eduardo Abella, President and CEO
TELEPHONE:	(212)-808-4848
FAX:	(212)-986-4939
NAME OF DEVICE:	Medge Platforms Sonocubic™ 3 D Ultrasound Software.
COMMON NAME:	3D Ultrasound Software

CLASSIFICATION: The Sonocubic™ Software is an accessory to Ultrasonic Pulsed Echo Imaging Systems which have been Classified as Class II Medical Devices (Ref. 21 CFR 892.1560, Radiology Devices).

INTENDED USE: The Medge Platforms Sonocubic™ 3D Ultrasound Software is indicated for the acquisition, retrieval, analysis, and storage of ultrasound images for computerized three dimensional image processing, from raw 2D ultrasound series.

DESCRIPTION OF THE DEVICE: The Sonocubic™ Software is designed to digitize images (obtained from video outputs of ultrasound scanners already legally marketed in the Ultrasound) into the Personal Computer memory using a frame grabber. The collection of digitized 2D frames form the raw volume data set.

This software renders a 3D surface using the raw volume and displays a 3D image on the PC screen that can be rotated and zoomed (ray tracing). The final results can be stored on disk or printed. Our product consists only a CD-ROM with the Sonocubic™ program, a users manual, and a hard key lock for copy protection.

STANDARDS: To the best of our knowledge no standards have been promulgated for Ultrasonic Pulsed Echo Imaging Systems.

SUBSTANTIAL EQUIVALENCE: The Medge Platforms Sonocubic™ 3D Ultrasound Software is substantially equivalent to the softwares used in:

1. The HDI 1500/SA 8800 Utrasound System with Multiplan marketed by ATL ULTRASOUND, INC. Bothell WA 98041-3003. 510(k) No. K994373.

and

2. FETAL ASSESSMENT CAP marketed by ACUSON CORPORATION, Mountain View, CA 94039-7393. 510(k) No. K992580.

SOFTWARE LEVEL OF CONCERN: Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2001

Mr. Gustavo Abella
Medge Platforms, Inc.
90 Park Avenue, 17th Floor
NEW YORK, NY 10016-1301

Re: K003672
Medge Platforms Sonocubic 3D Ultrasound Software
Dated: November 26, 2000
Received: November 28, 2001
Regulatory Class: II
21 CFR §892.1560/Procode: 90 IYO

Dear Mr. Abella:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K003672

510(k) Number (if known):

Device Name: Medge Platforms Sonocubic™ 3D Ultrasound Software

Indications For Use:

The Medge Platforms Sonocubic™ 3D Ultrasound Software is indicated for the acquisition, retrieval, analysis, and storage of ultrasound images for computerized three dimensional image processing, from raw 2D ultrasound series.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003672

(Optional Format 3-10-98)

Prescription Use /